HR 5866

Medical Device Patient Safety Act

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: May 30, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 1, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/5866

Sponsor

Name: Rep. Braley, Bruce L. [D-IA-1]
Party: Democratic • **State:** IA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 1, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 1995	Identical bill	**Dec 14, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 30, 2012)

Medical Device Patient Safety Act - Directs the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to establish a program to enhance the oversight by the Food and Drug Administration (FDA) of medical device recalls.

Requires the program to routinely and systematically assess: (1) information submitted to the Secretary pursuant to a device recall order issued under the Federal Food, Drug, and Cosmetic Act (FDCA); and (2) information required to be reported by a device manufacturer to the Secretary regarding the manufacturer's correction or removal of a device. Requires the Secretary to use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. Requires such program to be designed to identify such things as recall trends, the causes of recalls, and the time to complete a recall.

Requires the Secretary to develop explicit criteria for assessing whether a person subject to a recall order or the manufacturer's reporting requirement has performed an effective correction or removal action.

Requires the Secretary to document and publish specified information concerning termination of a recall.

Permits the Secretary to conditionally clear for introduction into interstate commerce for commercial distribution a medical device intended for human use if such medical device is cleared pursuant to specified FDCA reporting requirements concerning the introduction of devices into interstate commerce. Permits the Secretary, as part of such conditional clearance, to: (1) impose specified restrictions on the sale, distribution, or use of the device; (2) require specified labeling for the device; and (3) require the maintenance of specified records that enable the FDA to track the device and determine the safety and effectiveness of the device.

Actions Timeline

- **Jun 1, 2012:** Referred to the Subcommittee on Health.
- **May 30, 2012:** Introduced in House
- **May 30, 2012:** Referred to the House Committee on Energy and Commerce.